CLAIMS

1. A stable gene formulation which comprises a desired gene or a vector incorporated with a desired gene as well as at least one saccharide and/or at least one non-hydrophobic amino acid and/or at least one organic acid having two or more carboxyl groups except amino acids.

2. The gene formulation of claim 1, wherein the saccharide is a monosaccharide, a disaccharide, a oligosaccharide of trisaccharide and higher, or a sugar alcohol thereof

3. The gene formulation of claim 2, wherein the saccharide is glucose, galactose, fructose, sucrose, maltose, lactose, trehalose, sorbitol, or mannitol.

4. The gene formulation of claim 1, wherein the non-hydrophobic amino acid is glutamic acid, aspartic acid, or a salt thereof.

5. The gene formulation of claim 1, wherein the organic acid having two or more carboxyl groups is an organic acid having two or three carboxyl groups or a salt thereof.

6. The gene formulation of claim 5, wherein the organic acid having two or three carboxyl groups is citric acid or tartaric acid.

7. The gene formulation of ~~any one of~~ claims 1~~-6,~~ wherein the vector incorporated with a desired gene is a plasmid DNA.

8. The gene formulation of claim 1, which form is a solution, a gel, or a suspension, or which formulation is prepared through a preparation in a solution, gel, or suspension form, wherein the amount

of the saccharide, the non-hydrophobic amino acid, and the organic acid having two or more carboxyl groups except amino acids to the total amount of the solution, the gel or the suspension is about 1 w/v% or more.

9. The gene formulation of ~~any one of~~ claims 1~~–8,~~ wherein the formulation further comprises a substance accelerating an introduction of the gene into a cell.

10. The gene formulation of claim 9, wherein the substance accelerating an introduction of the gene into a cell is a cationic lipid, a cationic polymer, or a hydrophobic polymer.

11. The gene formulation of ~~any one of~~ claims 1~~–10,~~ wherein the formulation further comprises a pharmaceutically acceptable additive.

12. The gene formulation of claim 11, wherein the pharmaceutically acceptable additive is a biocompatible material.

13. The gene formulation of claim 12, wherein the desired gene or the vector incorporated with the desired gene is borne on a biocompatible material.

14. The gene formulation of claim 12 ~~or 13,~~ wherein the biocompatible material is a collagen, a gelatin, or a mixture thereof.

15. The gene formulation of ~~any one of~~ claims 1~~–14,~~ wherein the formulation is in a dried state.

16. The gene formulation of ~~any one of~~ claims 1~~–15,~~ which is obtainable by drying a preparation in a solution, gel, or suspension form which comprises a desired gene or a vector incorporated with a desired gene.

17. The gene formulation of claim 16, wherein the drying step

comprises a lyophilization.

18. A process for stabilizing a gene formulation derived from a gene preparation comprising a desired gene or a vector incorporated with a desired gene, which comprises adding at least one saccharide and/or at least one non-hydrophobic amino acid and/or at least one organic acid having two or more carboxyl groups except amino acids to the gene preparation.

19. A method for gene therapy, which comprises administering the gene formulation of ~~any one of~~ claims 1~~–17~~ to a living body.

20. A stable gene formulation which comprises a desired gene or a vector incorporated with a desired gene, at least one amino acid, and a collagen, or a gelatin.

21. The gene formulation of claim 20, which form is a solution, a gel, or a suspension, or which formulation is prepared through a preparation in a solution, gel, or suspension form, wherein the amount of the amino acid to the total amount of the solution, the gel or the suspension is about 1 w/v% or more.

22. The gene formulation of claim 20~~ or 21~~, wherein the formulation further comprises a substance accelerating the introduction of the gene into a cell.

23. The gene formulation of claim 22, wherein the substance accelerating the introduction of the gene into a cell is a cationic lipid, a cationic polymer, or a hydrophobic polymer.

24. The gene formulation of ~~any one of~~ claims 20~~–23~~, which comprises a desired gene or a vector incorporated with a desired gene borne on a collagen, or a gelatin.

25. The gene formulation of ~~any one of~~ claims 20-~~24~~, wherein the formulation is in a dried state.

26. The gene formulation of ~~any one of~~ claims 20-~~25~~, which is obtainable by drying a preparation in a solution, gel, or suspension form which comprises a desired gene or a vector incorporated with a desired gene.

27. The gene formulation of claim 26, wherein the drying step comprises a lyophilization.

28. A process for stabilizing a gene formulation derived from a gene preparation comprising a desired gene or a vector incorporated with a desired gene, and a collagen or a gelatin, which comprises adding at least one amino acid to the gene preparation.

29. A method for gene therapy, which comprises administering the gene formulation of ~~any one of~~ claims 20-~~27~~ to a living body.